PATENT APPLICATION NO. 09/902,176

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Stefan Schreiber et al.

Serial No.:

09/902,176

Filing Date:

July 10, 2001

Confirmation No:

7507

Art Unit:

1634

Examiner:

Sally A. Sakelaris

Title:

DIAGNOSTIC USE OF POLYMORPHISMS IN THE GENE CODING FOR THE TNF

RECEPTOR II AND METHODS FOR DETECTING NON-RESPONDERS TO

ANTI-TNF THERAPY

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

## INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.97(b)

Pursuant to the provisions of 37 CFR §§ 1.56, 1.97 and 1.98, and MPEP 609, Applicant submits herewith copies of the documents listed on the attached Form SB/08B "Information Disclosure Statement by Applicant."

## REMARKS

Consideration by the Examiner of each of the documents listed on Form SB/08B is respectfully requested. Applicant respectfully requests that a copy of SB/08B, as considered and initialed by the Examiner, be returned to the undersigned with the next Official Communication.

The filing of this Information Disclosure Statement shall not be construed as a representation that a search has been made. 37 CFR § 1.97(g). Furthermore, the filing of this

ATTORNEY DOCKET NO. 25481-P001US

PATENT APPLICATION NO. 09/902,176

Information Disclosure Statement shall not be construed to be an admission that the information

cited in this Statement is, or is considered to be, prior art, analogous art, or material to

patentability of this application, but the information has been cited to make it clear beyond all

doubt that Applicant's duty of disclosure has been complied with. 37 CFR § 1.97(h).

Applicant hereby submits that the claims of Applicant's above-referenced patent

application are patentably distinguishable from these references.

It is believed that no fees are due; however, the Director is hereby authorized to charge

any fees relating to this Information Disclosure Statement under 37 CFR § 1.17 to Deposit

Account No 23-2426 of WINSTEAD SECHREST & MINICK P.C.

Respectfully submitted,

Date: <u>December 14, 2004</u>

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PTO/SB/08B (04-03)
Approved for use through 04/30/2003. OMB 0651-0031
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Under the Paperwork Reduction Act of 1995, n d to respond to a collection of information unless it contains a valid OMB control number. Complete if Known Substitute for form 1449/PTO Application Number 09/902,176 INFORMATION DISCLOSURE **Filing Date** July 10, 2001 STATEMENT BY APPLICANT First Named Inventor Stefan Schreiber Art Unit 1634 (Use as many sheets as necessary) **Examiner Name** Sally A. Sakelaris Attorney Docket Number Sheet 2 25481-P001US 1 of

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		FABRIS, et al.; Tumor necrosis factor-alpha receptor II polymorphism in patients from southern Europe with mild-moderate and severe rheumatoid arthritis; Journal of Rheumatology; 2002 Sep; 29(9); 1847-50.	
		OGILVIE, et al.; Treatment of psoriatic arthritis with antitumour necrosis factor-alpha antibody clears skin lesions of psoriasis resistant to treatment with methotrexate; Br. J. Dermatol.; 2001 Mar; 144(3):587-9.	
		YEE AND POCHAPIN; Treatment of complicated sarcoidosis with infliximab anti- tumor necrosis factor-alpha therapy; Ann Intern Med. 2001 Jul 3; 135(1):27-31.	
		ARINGER, et al; Safety and efficacy of tumor necrosis factor alpha blockade in systemic lupus erythematosus: an open-label study; Arthritis Rheum. 2004 Oct; 50(10):3161-9.	
		BECKER, et al; TGF-Beta suppresses tumor progression in colon cancer by inhibition of IL-6 trans-signaling; Immunity, Vol 21, 491-501; October 2004, Cell Press.	
		ROSE-JOHN AND NEURATH, et al.; IL-6 trans-signaling: The heat is on; Immunity; Vol 20, 1-20, January 2004, Cell Press.	
		ATREYA, et al.; Blockade of interleukin 6 trans signaling suppresses T-cell resistance against apoptosis in chronic intestinal inflammation: Evidence in Crohn disease and experimental colitis in vivo; Nature Medicine, Volume 6, Number 5, 583-588; May 2000; Nature America, Inc.	
		RUTGEERTS, et al.; Treatment of active Chrohn's disease with onercept (recombinant human soluble p55 tumour necrosis factor receptor): results of a randomized, open-label, pilot study; Aliment Pharmacol Ther. 2003 Jan; 17(2):185-92.	
		DEN BROEDER, et al.; Long term anti-tumour necrosis factor alpha monotherapy in rheumatoid arthritis: effect on radiological course and prognostic value of markers of cartilage turnover and endothelial activation; Ann Rheum Dis 2002; 61:311-318.	
		CHOY, et al.; Efficacy of a novel PEGylated humanized anti-TNF fragment (CDP870) in patients with rheumatoid arthritis: a phase II double-blinded, randomized, dose-escalating trial; Rheumatology 2002; 41:1133-1137; British Society for Rheumatology.	

Examiner	Date	
Signature	Considered	

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

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	(USO as many sn	ocis as m	scessary)	Examiner Name	Sally A. Sakelaris	
Sheet	2	of	2	Attorney Docket Number	25481-P001US	

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		SANDBORN, et al; An Engineered Human Antibody to TNF (CDP571) for Active Crohn's Disease: A Randomized Double-Blind Placebo-Controlled Trial; Gastroentology 2001; 120:1330-1338; American Gastroenterological Association.	
		ELLIOT, et al; Randomized double blind comparison of chimeric monoclonal antibody to tumor necrosis factor alpha (cA2) versus placebo in rheumatoid arthritis. Lancet 344:1105-1110, 1994.	
		ELLIOTT, et al.; Repeated therapy with monoclonal antibody to tumour necrosis factor alpha (cA2) in patients with rheumatoid arthritis; Lancet, October 22, 1994; 344(8930):1125-7	

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